

**REMARKS**

Claims 1-22 are pending in the current application. No amendments are made to the claims. Applicants respectfully request reconsideration of the present application in view of the following reasons.

## REJECTIONS

### Rejection of Claims 1-22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 1-16 of co-pending published application 200[3]/0130167 and 2003/0134346

The Examiner has provisionally rejected Claims 1-22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 1-16 of co-pending published application 200[3]/0130167 [sic] and 2003/0134346, respectively. The Examiner states that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a biosensor using a mutated glucose binding protein.” Applicants respectfully traverse the rejection.

The claims, not the specification, are compared to determine whether double patenting exists. *See Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936 (Fed. Cir. 1992). [T]he test for double patenting is whether or not the subject matter of the patent claims is obvious from the subject matter of the claims at issue. *General Foods Corp. v. Studiengesellschaft Kohle mbH* 972 F.2d 1272, 23 USPQ2d 1839 (Fed. Cir. 1992). In *General Foods*, the court makes clear that the double patenting obviousness inquiry requires that entire claims be compared, and that it is not proper to select a portion of a claim, out of context, for analysis. *Id.*

A comparison of the instant claims and those of the co-pending published applications shows that the instant claims differ structurally and functionally from the co-pending claims. More specifically, the present invention claims a mutated binding protein with a reporter group attached thereto and an analyte permeable matrix that entraps or encapsulates the mutated binding protein. Claims 1-13 of co-pending published application 2003/0130167 recite a biosensor having a mutated binding protein and reporter group attached thereto and a sensor surface where the mutated binding protein is coupled to the surface through the thiol. (emphasis added) The sensor surface provides a detectable signal resulting from a change in refractive index when the mutated binding protein binds to analyte. The instant claims fail to recite a ‘sensor surface’ element. The instant claims are patentably distinct from co-pending published application 2003/0130167.

The claims of co-pending published application 2003/0134346 also fail to recite all the elements of the present claims. Claims 1-22 recite a biosensor having a mutated binding protein and reporter group attached thereto, such that the reporter group provides a detectable and reversible signal change related to varying concentrations when the mutated binding protein is exposed to varying glucose concentrations. The instant claims recite an analyte permeable matrix entrapping or encapsulating the mutated binding protein. The co-pending published application 2003/0134346 does not include an analyte permeable matrix. The instant claims are patentably distinct from co-pending Application 2003/0134346. Reconsideration and withdrawal of the double patenting rejection is respectfully requested.

Rejection of Claims 1-12 under 35 U.S.C. 102(e) as being anticipated by Hellinga

The Examiner has rejected claims 1-12 under 35 U.S.C. 102(e) as being anticipated by Hellinga. Applicants note that the Examiner did not specify which Hellinga reference is being cited. Applicants presumed that the Examiner was referring to US 6277627 (Hellinga '627) and has crafted its response in this context.

The Examiner states, "Hellinga teaches a glucose biosensor comprising a genetically engineered glucose binding protein (GBP hereafter) that has been read on the claimed mutated binding protein. There are luminescent labels, acrylodan and IANBD (see figures 2- 3 and col. 61lines 41+), covalently attached to the GBP that emit light at a wavelength greater than 600nm. Column 9 lines 6+ teach cysteine mutations at the claimed "152" position." Applicants respectively traverse the rejection.

As the Federal Circuit has held in *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (1987), "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Hellinga is silent to the claimed polymer support, the claimed siloxanes and the claimed silicone additives. This is acknowledged by the Examiner in the Office Action at page 5. Applicants claim is explicit in its teaching of an analyte permeable matrix entrapping or encapsulating mutated binding protein. Hellinga '627 fails to teach or suggest an analyte permeable matrix entrapping or encapsulating a mutated binding protein. Hellinga '627 fails to

anticipate the claimed invention because it fails to teach all the elements of the claim.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 1-7, 10-16 and 19-20 under 35 U.S.C. 102(e) as being anticipated by Lakowicz

The Examiner has rejected claims 1-7, 10-16 and 19-20 under 35 U.S.C. 102(e) as being anticipated by Lakowicz et al. [US 6197534] (Lakowicz '534) stating, "Lakowicz et al. teaches an engineered or modified protein that can be used for the detection of glucose in a biosensor. Column 5 lines 27 + teach the placing a cysteine residue at position "182" and covalent attachment which is identical to that claimed. Column 5 lines 4+ teach use of the claimed labels such as acrylodan, fluorescein, rhodamine, etc. Column 11 lines 35+ teach use of a PVA film." Applicants respectively traverse the objection.

Lakowicz '534 fails to teach an analyte permeable matrix encapsulating mutant protein as recited in the instant claims. Lakowicz '534 teaches the use of a PVA film containing an energy accepting ruthenium dye adjacent to a solution containing the mutant protein. This PVA film/energy accepting ruthenium dye is not attached to nor entrapping or encapsulating the mutated protein or even in contact with the protein solution. Lakowicz '534 fails to anticipate the claimed inventions because it fails to teach all of the elements of the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 17-18 and 21-22 under 35 U.S.C. 103(a) over Lakowicz

The Examiner has rejected Claims 17-18 and 21-22 under 35 U.S.C. 103(a) as being unpatentable over Lakowicz et al., stating "Lakowicz et al. are silent to the claimed siloxanes condensed with at least one water soluble organic polyol component and the claimed silicone additives." The Examiner, relying on *In re Leshin* (125 USPQ 416), concludes that "[s]iloxanes and silicone materials are widely used in the art because of their inert properties. It would have been within the skill of the art to modify Lakowicz et al. and use the above siloxane and silicone materials to gain the above advantages and further in view of *Leshin* as selection of a material based upon its suitability of intended use." Applicants respectively traverse the objection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See MPEP 2143*. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner has not cited any references or provided sufficient reasoning to meet these criteria, and thus has not fulfilled the burden of proving that the claims are obvious over the cited reference. As discussed above, Lakowicz '534 fails to teach an analyte permeable matrix encapsulating mutant protein. Lakowicz '534 also fails to teach or suggest the use of siloxanes condensed with at least one water-soluble organic polyol component. Applicants' claim entrapment or encapsulation *of the protein* having the reporter group attached thereto. Lakowicz '534 fails to teach each element of the claim.

The Examiner asserts that "[s]iloxanes and silicone materials are widely used in the art because of their inert properties." However, there is no suggestion or motivation in Lakowicz '534, or expressed by the Examiner's personal knowledge that a material's "inertness" would or could lead one skilled in the art in selecting materials for entrapping or encapsulating protein and providing analyte permeability.

Applicant's request the Examiner provide an affidavit or declaration setting forth specific factual statements and explanation to support the assertion that "siloxane or silicone materials" would provide any suggestion or motivation to use same in entrapping or encapsulating proteins, and/or providing for analyte permeability. *See* 37 CFR 1.111(b); 37 CFR 1.104(c)(2); *see also Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence [in the record] in support of these findings" to satisfy the substantial evidence test). *Id.*; *see* 37 CFR 1.104(d)(2). As the references, either alone or in combination, fail to teach all of the elements of the claimed invention, and there is no motivation to modify the references to achieve the presently claimed invention, Applications respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 13-22 under 35 U.S.C. 103(a) over Hellinga and Lakowicz

The Examiner has rejected Claims 13-22 under 35 U.S.C. 103(a) as being unpatentable over Hellinga '627 alone or in view of Lakowicz '534, stating Polymers, siloxanes and silicones materials are widely used in the art because of their inert properties. It would have been within the skill of the art to modify Hellinga and use the above siloxane and silicone materials to gain the above advantages and further in view of Lesin as selection of a material based upon suitability of intended use," and "Lakowicz et al. above teaches it is known to place a glucose sensor on a PVA film. PVA is inexpensive, inert and readily available. It would have been within the skill of the art to modify Hellinga in view of Lakowicz et al. and use a PVA support to gain the above advantages." Applicants respectfully traverse the rejection.

The Examiner has not cited any references or provided sufficient reasoning to meet these criteria, and thus has not fulfilled the burden of proving that the claims are *prima facie* obvious over the cited references. Hellinga '627 fails to teach or suggest the analyte permeable matrix of the currently pending claims. As discussed above, Lakowicz '534 in col. 11, lines 35+ teaches the use of a PVA film containing a ruthenium dye *adjacent* to the mutated protein, and in fact, the PVA film is placed *outside the cuvette* containing the mutant protein solution. Lakowicz '534 also fails to teach or suggest the use of siloxanes condensed with at least one water-soluble organic polyol component. Applicant's claim is explicit in its teaching entrapment or encapsulation of the protein in an analyte permeable matrix. All of the references, alone or in combination fail to teach the analyte permeable matrix element and thus fail to teach each and every element of the claim.

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). The Examiner fails to show that there is any motivation to combine, or any reasonable expectation of success, to modify Hellinga '627 or its combination with Lakowicz '534, to use siloxane and silicone materials (or PVA) as a material based upon suitability of intended use. Specifically, siloxane's inertness or PVA's inexpensiveness, inertness, and availability, fail to provide the requisite suggestion or motivation as to the

selection of these materials for entrapment or encapsulation of protein, and for analyte permeability. There is no teaching in either reference or expressed knowledge of the Examiner to suggest interchangeability of silicone materials and PVA, suitability for protein entrapment, or suitability for analyte permeability. Applicant's therefore challenge Examiners' factual assertion as not properly officially noticed, or not properly based upon common knowledge, and respectfully request the Examiner support the finding with adequate evidence/affidavit under 37 CFR 1.104(d)(2).

Accordingly, because the Examiner has failed to meet the criteria necessary to establish a case of prima facie obvious, the Examiner's rejection of the claims under 35 U.S.C. § 103(a) is improper. Reconsideration and withdrawal of the outstanding obviousness rejection is respectfully requested.

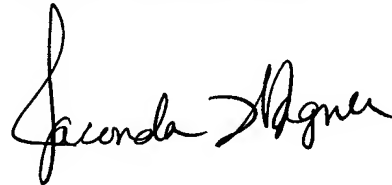
### CONCLUSION

Applicants believe that the present application is now in condition to allowance. Favorable reconsideration of the application is respectfully requested. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Jaconda Wagner (Reg. No. 42,207) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application. Please note that attached hereto is a marked-up version of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-1666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jaconda Wagner", written in a cursive style.

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